

RESOLUTION No. 29

Register of Diagnostic Kits Validated and Certified by the OIE

CONSIDERING THAT

1. During the 71st General Session of the OIE in May 2003, the International Committee adopted Resolution No. XXIX endorsing the principle of validation and certification of diagnostic assays (test methods) for infectious animal diseases by the OIE and giving a mandate to the Director General of the OIE to set up the specific standard procedures to be used before the final decision on the validation and certification of a diagnostic assay is taken by the OIE International Committee,
2. The Resolution has established that 'fitness for purpose' should be used as a criterion for validation,
3. The aim of the procedure for diagnostic kits is to produce a register of recognised assays for OIE Member Countries and for diagnostic kit manufacturers,
4. OIE Member Countries need assays that are known to be validated according to OIE criteria in order to improve the quality of assays, to ensure that the test can be used to correctly establish animal disease status and to enhance confidence in assays,
5. The OIE register of recognised assays provides greater transparency and clarity of the validation process, and a means for recognising those manufacturers that produce validated and certified tests in kit format,
6. According to the OIE Standard Operating Procedure, registration of the diagnostic kits included in the OIE Register has to be renewed every five years,
7. During the 74th General Session of the OIE, the International Committee adopted Resolution No. XXXII on the importance of recognising and implementing OIE standards for the validation and registration of diagnostic assays by Member Countries,

THE ASSEMBLY

DECIDES THAT

1. In accordance with the recommendation of the OIE Biological Standards Commission, the Director General add the following to the register of diagnostic kits certified by the OIE as validated as fit for purpose:

| Name of the diagnostic kit | Name of the Manufacturer | Fitness for purpose |
|--|--------------------------|---|
| Newcastle Disease Virus antibody detection ELISA | BioChek UK Ltd | Fit to detect Newcastle disease virus specific IgG antibodies in chicken sera and for the following purposes: <ol style="list-style-type: none">1. To demonstrate historical freedom from infection in a defined population (country/zone/compartments/flock);2. To determine immune status in individual animals or populations (post-vaccination);3. To monitor infection or disease in unvaccinated populations;4. To estimate prevalence of infection to facilitate risk analysis in non-vaccinated populations (surveys/ flock health schemes/disease control). |

2. In accordance with the recommendation of the OIE Biological Standards, the Director General renew for a period of five additional years the inclusion in the OIE Register of the following diagnostic kit certified by the OIE as validated as fit for purpose:

| Name of the diagnostic kit | Name of the Manufacturer | Fitness for purpose |
|----------------------------|--------------------------|---|
| TeSeE™ Western Blot | Bio-Rad | <p>Fit for the post-mortem detection of transmissible spongiform encephalopathies (TSEs) in cattle (bovine spongiform encephalopathy, BSE), in ovines and caprines (BSE and scrapie), and in cervids (chronic wasting disease, CWD), and for the following purposes:</p> <ol style="list-style-type: none"> 1. To confirm TSE suspected positive samples detected at the screening laboratories in countries with active/passive surveillance programmes. Any sample with a negative result according to the TeSeE™ WESTERN BLOT assay interpretation criteria, following a positive rapid test result, should be tested with one of the other OIE certified confirmatory methods, Immunohistochemistry (IHC) or SAF-Immunoblot; 2. To confirm the prevalence of infection with one of the TSE associated diseases (BSE, scrapie, CWD) in the context of an epidemiological survey in a low prevalence country; 3. To estimate prevalence of infection to facilitate risk analysis (e.g. surveys, implementation of disease control measures) and to assist the demonstration of the efficiency of eradication policies. |

(Adopted by the World Assembly of Delegates of the OIE on 28 May 2014)